



House of Commons
Science and Technology
Committee

**Watching the Directives:
Scientific Advice on the EU
Physical Agents
(Electromagnetic Fields)
Directive: Responses to
the Committee's Fourth
Report of Session 2005–06**

Sixth Special Report of Session 2005–06

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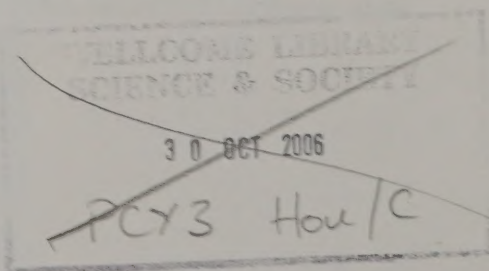
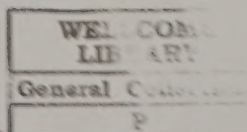
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Sixth Special Report

On 29 June 2006 the Science and Technology Committee published its Fourth Report of Session 2005–06, *Watching the Directives: Scientific Advice on the EU Physical Agents (Electromagnetic Fields) Directive* [HC 1030]. On 10 October 2006 the Committee received a memorandum from the Government which contained a response to the Report. The memorandum is published without comment as an appendix to this Report.

The Committee also received a response from the Health Protection Agency which is also published without comment as an appendix to this Report.

Appendix 1

Government Response

This is the Government's response to the Select Committee's report. It covers those recommendations addressed to the Government and its agencies, particularly the Health and Safety Commission and Executive (HSC/E). The Government is grateful to the Committee for its thorough examination of the issue, and acknowledges the criticisms made in the report of the process of negotiating the Directive. The HSC/E are committed to learning lessons arising from this episode and have brought the report and lessons to learn to the attention of all HSE staff. Some changes have already been made, and further work is taking place to ensure that similar problems do not occur in the future.

1. We were alarmed to discover that the European Council was prepared to rely on a ten-year-old risk assessment to inform legislation in an area of rapidly developing science and technology. We welcome the moves taken to ensure that new proposals are accompanied by new impact assessments, as long as these are taken to include revived Directives such as this one. (Paragraph 29)

The Government was also extremely unhappy with the ten-year-old risk assessment and raised this matter frequently during negotiations. However it received no support from other Member States nor the European Commission.

The UK Government has been pressing the European Commission for many years to carry out more thorough impact assessments on legislative proposals. Since 2005 all new major EC legislative and policy defining proposals have been required to have full impact assessments, and the Government is now pressing strongly to improve the quality of these assessments.

2. We conclude that the HSE did not apply the necessary expertise to its assessment of the impact of the Directive. We recommend that the Health and Safety Executive ensures that regulatory impact assessments on EU proposals are conducted in a comprehensive manner, on a sector-by-sector basis, with care being taken to address the broader impact, rather than just the costs, of the legislation. (Paragraph 32)

All new major EC legislative and policy defining proposals since 2005 have been required to have full impact assessments.

Domestically, HSE's record on RIAs is recognised by the National Audit Office and others as strong. But there is room for improvement. We are currently seeking to improve the timing at which draft RIAs are produced by specifically developing and involving the outcomes of the HSE's horizon scanning. This will allow HSE to identify developments which may require intervention and use the impact assessments developed in parallel with policy proposals. At EU level, in future HSE will instruct HSE negotiators to press strongly for better quality EC assessments to be done, while recognising that this is not straightforward in fast moving dossiers.

Additionally, there are a number of projects within the EU to assess and evaluate the impact of legislation. UK is leading the way by assisting them on evaluating some Directives to show how to build up the evidence base to assure learning from experience. An example for the work in the EU is the joint evaluation of member states' legislation which implements the EU Display Screen Equipment Directive (90/270/EEC). Here UK has been leading on the evaluation guidelines and aims to use this as a good practice example for better regulation in the EU.

3. It is deeply regrettable that the impact of the Directive on MRI procedures was not established before the Directive was adopted. This case study illustrates the potential consequences of the failure of policy makers to seek comprehensive scientific advice early in the policy formulation process and to commission the necessary research to inform this process where uncertainty or gaps in knowledge exist. (Paragraph 40)

UK negotiating lines were informed by consultation with stakeholders, as is normal, but HSE recognises that, on this occasion, it was inadequate. There are many examples of good stakeholder engagement and consultation by HSE but, we acknowledge, improvements can still be made. The steps HSE is taking are described more fully in response to Recommendation 14 below, HSE has already started a review of its consultation procedures. This will seek to improve its ways of working with stakeholders, including the use of scientific advice.

4. For MRI at least, we do not believe that there was a strong enough case for enshrining exposure limits in a Directive. We agree with the Government that existing guidelines are sufficient. The Directive will, at best, impose burdens on employers and, at worst, inhibit the use of valuable diagnostic procedures and important research. (Paragraph 42)

Whilst it is true that the existing guidelines were considered sufficient, the Directive is not expected to impose significant burdens on employers who are already complying with them. The Committee are aware of work under way by HSE to measure the impact of the Directive on MRI and seek a solution to any problems.

In relation to the scientific review that underpins the NRPB guidance, the Health Protection Agency (HPA) notes in the Committee's report that "the MR community agrees that the NRPB literature review carried out in 2004 is widely regarded as a definitive summary of the state of the science". The Committee also noted that the report highlighted uncertainties in the evidence base and the need for further research, particularly on any long-term effects of exposure to static fields (paragraph. 26).

5. While there should be an obligation to reduce risks to a reasonable level, to actually pursue the “lowest achievable limit” would entail health and safety practices which most would consider unnecessary and economically unviable, if not counterproductive in certain circumstances. Risks need to be balanced against gains, rather than necessarily minimised. (Paragraph 46)

The Government agrees that inappropriate risk management, whether excessive risk aversion or inaction in the face of more serious risks, is damaging. The Government encourages the use of judgment by those who are competent and best placed to manage risks, i.e. those whose activities give rise to the risks in the first place.

The HSE and HSC are promoting a sensible approach to managing risks, where people seek to manage risk responsibly and proportionately, not eliminate it altogether. In August 2006¹ they launched a set of principles of sensible risk management agreed with a very wide range of stakeholder organisations. HSE is working to ensure that the spirit of these principles is fully embedded in its work.

6. Regardless of the impact on current MRI procedures, any attempt to consider the health of workers in isolation from all other factors would be against the spirit of the precautionary principle, as set out by the Commission. We hope that the agreement of the Commission to undertake further work on the potential impact of the Directive indicates a willingness to accept the need for a wider risk-benefit analysis. (Paragraph 48)

The Government continues to encourage improved risk-benefit analysis by the European Commission, and is involved in work to help it to do so.

7. We recommend Government and its agencies desist from using the term “precautionary principle” in order to explain policy decisions or judgments. We also urge Ministers to propose a similar approach in discussions in the EU Council. (Paragraph 51)

The Government believe the precautionary principle is valuable in dealing with uncertainty. There is no single definition for the Precautionary Principle. However, in the context of the Treasury’s guidance *The Green Book: Appraisal and Evaluation in Central Government*² it is defined as, “The concept that precautionary action can be taken to mitigate a perceived risk. Action may be justified even if the probability of that risk occurring is small, because the outcome might be very adverse”. In practice the Precautionary Principle is interpreted as a flexible precautionary approach to enable innovation and learning in circumstances of significant complexity and uncertainty. As such, the supplement to *The Green Book Managing risks to the public: appraisal guidance* advises that precautionary approaches should be adopted alongside research and monitoring, and that highly restrictive or expensive precautionary interventions should be reviewed on a regular basis in the light of research findings and new data.

8. We are surprised that neither the Chief Scientific Adviser at the Department of Health nor the Chief Scientist at the Health and Safety Executive was involved at any

¹ <http://www.hse.gov.uk/risk/index.htm>

² http://www.hm-treasury.gov.uk/media/785/27/Green_Book_03.pdf

stage in providing advice on the Directive, particularly in view of the high levels of expenditure on MRI equipment at DH. If they are not involved in the policy making process on a subject with such a heavy reliance on science, it is difficult to see how they were operating effectively. We recommend that the DH and the HSE take steps to ensure that their respective chief scientists are actively and routinely involved in the provision of advice informing policy. (Paragraph 54)

HSE is committed to evidence-based policymaking supported by the best available scientific advice, including that of its in-house experts and external expertise. It has put in place a quality system to secure effective implementation of the Chief Scientific Adviser's Guidelines including guidance on how to resolve conflicting scientific opinion. Reviews undertaken to date show good compliance with this guidance but the review programme will be broadened and strengthened in the light of the Committee's findings, and HSE will urgently review its performance across a range of the Directives that it is negotiating or implementing.

The new HSE Chief Scientist and DH Chief Scientist are already considering how to work together more effectively on matters of mutual interest.

9. Given that the concerns raised about the Directive in 2003 coincided with its consideration in the European Council, and that they came from medical practitioners well placed to provide advice, we find the response by the HSE and NRPB/HPA to them highly disappointing. This reaction was characterised by an instinctive and dismissive resistance rather than an attempt to engage and examine. Both organisations acted in contravention of the guidelines laid down by the Government Chief Scientific Adviser. (Paragraph 60)

HSE recognises that, although efforts were made to engage with all stakeholders, in one area, it did not succeed in properly reflecting their needs. It acknowledges the need to review the way in which it consults and whether it is seen by those consulted to have properly considered their views. HSE has already started a review of its internal consultation procedures. This will be brought to a conclusion this autumn, with new internal guidance linked to new Cabinet Office best practice guidance. This will address issues such as:

- the importance of early external consultation on the basis of a full stakeholder analysis beyond the customary consultees;
- the standard of scientific evidence to support consultees' submissions and the help HSE can provide in this process;
- the need to comply with the Chief Scientific Adviser's Guidelines and involve the Chief Scientist in scientific dossiers, especially if there is conflicting scientific advice;
- the desirability of talking to stakeholders (for example SMEs or professional groups) in addition to the more usual written/internet consultations
- how HSE reports the results of consultation; and

- how to handle disagreements with stakeholders and the importance of flagging these up within HSE and HSC, and making it clear to stakeholders that they can escalate their case.

In the interim, HSE's web-based guidance on handling EU negotiations is being amplified to bring out the headline points for EU negotiators.

For its part, the Health Protection Agency (HPA, formerly NRPB) has already posted on its web site a response to the issues raised³ and has said it will study the points made by the Committee carefully and ensure that any lessons are learnt from this episode.

10. It is extremely worrying that the HSE managed to outline a policy to the MR community in the UK which was the precise opposite of the one it had been pursuing in Brussels during negotiations. That the HSE could be contradicting itself for such a long period suggests some quite astonishing failings in management and internal communications. We recommend that the HSE seeks to discover how this situation could persist for so long, and takes appropriate steps to ensure that there can be no repeat. (Paragraph 61)

11. We welcome the frank admission of the failings in consultations on the Directive by the Minister and, more pertinently, by the Health and Safety Executive. (Paragraph 62)

It is important to recognise that the discussions within the UK aimed to engage the MRI community, principally, to explore the consequences of the removal of the static field values, and help the MRI community and others identify solutions in relation to more generic duties under existing health and safety legislation, in particular the need to conduct or review risk assessments in the light of technological developments. Nevertheless, it is clear that HSE's approach in these circumstances was not sufficiently transparent and consequently its policy position was not perceived correctly or consistently. The review on consultation (see response to recommendation 14) will address this.

HSE is also seeking to strengthen senior management oversight and consider how best to work across the different specialisms on negotiations of Directives. This should address the adequacy of plans for stakeholder engagement and consultation, the proper resourcing of the negotiation to ensure the right balance of policy and specialist input, identification of potentially difficult issues, the appropriate involvement of HSC, Ministers and Parliament, and so on. Also, HSE already has a review under way into ways in which decisions are made, and information flows. The HSE Board is committed to act on the results of these reviews.

12. The Government was badly let down by the HSE and NRPB, not only by their failure to consult sufficiently widely but also by their failure to advise Ministers on the concerns being raised. When informed of these concerns, Ministers acted with commendable speed to investigate further. We welcome the commitment by the Government to rectifying these earlier failings by working closely with the MR community. (Paragraph 64)

3 http://www.hpa.org.uk/hpa/news/articles/press_releases/2006/060629_physical_agents.htm

As has been made clear, the Government acknowledges that there are lessons to be learned from the handling of this Directive and took action as soon as it was informed of the concerns.

HSE is committed to finding a solution to the problems in partnership with the MR community and other government bodies.

The HPA has a policy of consulting widely on its formal advice, for example on exposure guidelines for EMFs. NRPB did raise with HSE the concerns of the medical community about the possible, but unproven implications of the Directive for exposures of staff. HPA is unaware of any specialist issues that were referred to it by HSE for consultation with relevant public bodies and stakeholders.

13. We conclude that the professional bodies, the Wellcome Trust, and the MRC were insufficiently pro-active in identifying the implications of the Directive and informing their communities, and politically ineffective in communicating these concerns in Westminster and Brussels. We recommend that the professional bodies and research funders re-examine the development of their links with each other and explore ways in which they can work together to improve their political effectiveness. (Paragraph 68)

While Government recognises that the formal route for communicating concerns is normally through Government and that the relevant Government Departments have a role to play in alerting stakeholders (including funders) to developments that may affect them, we do recognise that these stakeholders have been criticised and wish to encourage them to do better in this area. The Government welcomes the action they are taking in this regard.

The Research Councils (RCs) are developing additional mechanisms to improve political effectiveness, increasing direct contact with MPs and MEPs. .

At the EU level a new post has been established within their UK Research Office (UKRO) in Brussels to monitor EU policy in relation to research and proposed legislation.

The Research Councils also work with other bodies through the European Liaison Group (ELG), which monitors European activity in the Biosciences; recently the ELG has established links with the House of Lords European Union Committee secretariat. ELG members include ABPI, BIA, AMRC, AMS, BBSRC, Biosciences Federation, British Ecological Society, British Heart Foundation, Cancer Research UK, MRC, Royal Society, Royal Society of Chemistry, Universities UK and Wellcome Trust.

14. We recommend that the Department of Health and the Medical Research Council review their representation on the Interdepartmental Liaison Group on non-ionising radiation to ensure that the Group is provided with the necessary breadth of expertise and that they give due consideration to the issues raised by the Group. (Paragraph 70)

The Department of Health will review and strengthen the horizon scanning capabilities of the Interdepartmental Liaison Group on Non-ionising Radiation.

15. We recommend that the Office of Science and Innovation reviews its horizon scanning activities in respect of EU legislation, in consultation with the Research Councils. We believe that there is a strong case for the UK Research Office to perform a horizon scanning function on behalf of the Research Councils. (Paragraph 72)

The Office of Science and Innovation's (OSI) Horizon Scanning Centre has been structured to meet the commitment made in the Government's 10 year Science and Innovation Investment Framework (July 2004)⁴, that is to "feed directly into cross-government priority setting and strategy formation...this will not replace the requirement for effective horizon scanning in departments...rather, it will provide a higher-level strategic context to those other activities". It is for government departments and agencies to undertake horizon scanning on legislative and other issues within their areas of responsibility, and to involve stakeholders (including RCs) as part of this process. To attempt to undertake this centrally could not match levels of subject expertise in individual departments/agencies and would create needless duplication as well as reducing incentives for departments/agencies to raise their own horizon scanning capabilities. This latter goal is ultimately the best protection against the issues raised by the Committee. In order to help departments to raise their horizon scanning capabilities, OSI has a 'best practice' workstream which provides guidance, training and networking opportunities.

The point regarding UKRO is covered under Recommendation 19.

16. We recommend that UKREP reviews its channels of communication with the scientific community in the UK and considers developing some capability for direct links, on a systematic basis, or at least on an *ad hoc* basis in response to the introduction of proposals. (Paragraph 75)

UKRep represents UK interests in the EU including taking part in negotiations preparing draft legislation for decision by Member States' Ministers in the Council. In negotiations such as the one on the Worker Protection Directive on Electromagnetic Fields UKRep negotiates within parameters agreed by Ministers across Government and uses detailed instructions prepared by the relevant government department. Departments prepare instructions that are in line with Government policy on an issue and, where relevant, take account of information or advice from scientists or other experts.

Consistent with these instructions, UKRep maintains extensive contacts with external stakeholders, both those based in Brussels and those visiting. These stakeholders include other Member States, the European Commission and the European Parliament, and representatives of, among others, British business and workers, the UK regions, British Parliamentarians, lobbyists, consultants, academics and the media. These stakeholders may also include, as appropriate to the subject, representatives of the scientific community.

17. We welcome the commitment of funds from the HSE and the MRC to a programme of research on the potential impact of the Directive on MRI procedures. In the meantime, we recommend that the Government does not prioritise the Directive for implementation through secondary legislation. (Paragraph 76)

The Government agrees with the Committee's recommendation. HSE's main priority in implementing the Directive at this time is work to seek an appropriate solution for the MRI issue.

18. We welcome the establishment of the joint working group by the Commission to examine new evidence and hope that it is a genuine attempt to inform the

⁴ http://www.dti.gov.uk/science/science-funding/framework/next_steps/page28988.html

implementation of the Directive rather than simply a device to mollify the critics. We urge the UK Government to ensure that this work is well informed by the further research in the UK, and is completed in time for decisions on the implementation or amendment of the Directive to be taken before April 2008. If new research demonstrates a clear need for the Directive to be amended, for example to exclude MRI from its scope, the UK Government should seek this solution, rather than relying on non-enforcement. At the very least, the Government should press for a full impact assessment when the Directive is reviewed in 2009.

The Government will bring the outcomes of the current research to the European Commission's attention and urge it to make any necessary changes quickly at European level.

On enforcement, the Health and Safety Commission has endorsed an evidence-based intervention strategy *Sensible health and safety—the regulatory methods used in Great Britain*⁵, and HSE uses a risk-based approach to target its inspection activity. If necessary the Government will use the opportunity of the 2009 review to press for thorough evaluation of the impact of the Directive.

5 <http://www.hse.gov.uk/aboutus/hsc/sensiblehealthandsafety.pdf>

Appendix 2

Response from the Health Protection Agency

The Health Protection Agency (HPA) notes that the Science and Technology Committee (STC) has chosen to examine how scientific advice was used by Government to inform and advise on legislation emanating from the EU, in particular in relation to the Physical Agents Directive¹. The purpose of the Directive is to provide minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields (EMFs)).

The Radiation Protection Division of the HPA, previously the National Radiological Protection Board (NRPB), has the responsibility to advise government departments on the health effects of exposure to ionising and non-ionising radiations. It also gives independent advice on exposure guidelines. In addition it carries out research to underpin its advice and provides a range of technical services for which it makes charges.

HPA understands the concerns expressed by the Medical Resonance Imaging (MRI) community about possible, but as yet unproven implications of the Directive for exposures of staff during some diagnostic procedures. It has supported the need for occupational exposure assessments, particularly during interventional procedures (where staff are in close proximity to patients), and has consistently called for more research on the effects of exposures to MRI.

HPA is aware of the rapidly developing technology now used for medical diagnosis and treatment that can involve exposures to both ionising and non-ionising radiations in complex fields. It has established a Department to specifically address protection issues related to such medical exposures.

Exposure guidelines and their scientific basis

HPA agrees with the Committee's view that there needs to be extensive consultation in relation to guidelines for limiting exposure to electromagnetic fields (para. 5 of STC Report).

The most recent scientific review of the health effects of EMFs and advice on exposure guidelines for EMFs published by NRPB was in 2004^{2,3}. This followed an extensive consultation exercise that involved review by experts, discussions with representatives from government departments, an open public meeting, and consultation with stakeholders on a draft report posted on the NRPB web site. The consultation procedure adopted by NRPB appears consistent with advice from the Office of Science and Technology (OST) to Government departments *on Guidelines for Scientific Advice and Policy Making* (para. 52).

The advice from NRPB in 2004 recommended the adoption in the UK of the guidelines from the International Commission on Non-Ionizing Radiation Protection (ICNIRP). The guidelines refer to exposures of people (not just workers) to EMFs at various frequencies and are not aimed at specific industries or practices (para. 8). HPA notes that the STC considers that the guidance NRPB (now HPA) has issued has been widely accepted by Government, professional bodies and industry (para. 5).

As part of its review of the scientific evidence, NRPB invited distinguished UK experts in neurophysiology to join an *ad hoc* Weak Electric Fields Group whose remit was to “review the neurophysiological evidence for effects of induced electric fields and currents that could provide a basis for revised guidance on human exposure to time-varying electric and magnetic fields below 100 kHz”. The Group’s position statement, published as an Appendix to the NRPB review of scientific evidence, provided important support for the recommendation to adopt the ICNIRP guidelines for EMFs. The STC report refers to this Group as being asked to speculate about possible levels of field strength at which there were detectable effects on the body (paragraph 17). This was not the case.

In relation to the scientific review that underpins the NRPB guidance it is noted in the STC report that “the MR community agrees that the NRPB literature review carried out in 2004 is widely regarded as a definitive summary of the state of the science”. The STC also noted that the report highlighted uncertainties in the evidence base, and the need for further research, particularly on any long-term effects of exposure to static fields (paragraph. 26).

HPA supports the view expressed by the STC, in common with a recommendation in the Stewart Report on Mobile Phones and Health 2000, that “We are not convinced of the need to incorporate ICNIRP guidelines into statutes. We believe that they are liable to change as more scientific information on possible health effects becomes available”. (paragraph. 42). This has been very well demonstrated by the comprehensive reviews of the health effects of EMFs published by NRPB/HPA and others over the last twenty years. NRPB/HPA has never called for its advice on EMF exposure guidelines to be incorporated into legislation.

Physical Agents Directive (EMF) and the legislative process

The STC report expresses concern about the implications of the Directive for work with MRI equipment. It suggests that Government “relied on the HSE and the NRPB/HPA to advise and to negotiate on the Directive during the legislative process” (paragraph. 55).

The Agency will study the points made by the Committee carefully and ensure that any lessons are learnt from this issue. However, NRPB/HPA played no part in the legislative and negotiation process related to the development and agreement on the Directive; this was the responsibility of Government Departments. HPA is unaware of any specialist issues that were referred to it by HSE for consultation with relevant public bodies and stakeholders (paragraph. 57).

NRPB did, however, organise a meeting with representatives of the MRI medical community and members of the independent Advisory Group on Non-ionising Radiation (AGNIR) in London on 11 June 2003 to examine ways to promote research on any health effects of exposures to MRI. This related to a request from the NRPB Board for AGNIR to review any health effects of exposure to static fields. That review by AGNIR is now underway. At the meeting in London the medical representatives expressed their concern about the implication of the Directive for exposures of staff to static fields during MRI procedures. Subsequent to the meeting they wrote (12 June 2003) to NRPB, at its request, expressing the concerns raised. This letter was passed to representatives of government departments at a meeting of the Liaison Group on Non-ionising Radiation (NIRLG) on 19 June 2003. The concerns about MRI that had been raised were covered by NRPB staff at the NIRLG meeting and this is recorded in the Minutes.

The NRPB was commissioned by HSE in 1993 to provide a report reviewing data on exposures to EMFs across the spectrum in workplaces (paragraph. 30). The NRPB report included some information on exposures in the vicinity of MRI equipment but the information available then was limited. A further report was commissioned by HSE in 2001 to update the earlier report. However, the specification of the later work was to use measurement information already obtained by NRPB through commercial contract work carried out in the intervening period. The NRPB measurements had been made at the request of a range of industries, and did not include any measurements on MRI. For this second review HSE did not require a comprehensive literature review to be carried out.

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